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**UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF CALIFORNIA**

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| Austin M. Higley, *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>California State University, *et al.*,<br><br>Defendants. | No. 2:21-cv-01126-TLN-JDP<br><br>**FEDERAL DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS**<br><br>Prelim. Inj.: August 19, 2021, 2:00 PM (vacated)<br>Mot. to Dismiss: September 2, 2021, 2:00 PM<br>District Judge: Hon. Troy L. Nunley |

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## INTRODUCTION

Federal Defendants include public health agencies charged with evaluating the safety, purity, and potency of potential COVID-19 vaccines and making vaccination recommendations to the public. This rigorous evaluation process involves scientific determinations and technical judgments that lie at the core of these agencies' expertise. Nevertheless, students lacking such expertise seek to interfere with that process, requesting a preliminary injunction against approval of a vaccine absent pre-screening and exclusion of persons who have or have had COVID-19. But this case fails for many jurisdictional reasons, so the Court should dismiss the claims against Federal Defendants on that basis. Even if the Court decides it has jurisdiction, the Court should deny Plaintiffs' motion because they cannot meet the standard for such extraordinary relief.

## BACKGROUND

The U.S. Food and Drug Administration (FDA) has authority to review and approve "biological products," including vaccines. *See* 42 U.S.C. § 262(a)(1), (i)(1). In an emergency, FDA may authorize the emergency use of vaccines under a different pathway. *See* 21 U.S.C. § 360bbb-3. Invoking that authority, FDA has granted "emergency use authorization" (EUA) to three COVID-19 vaccines during the pandemic.[1] FDA is currently evaluating at least one biologics license application (BLA) seeking approval of a COVID-19 vaccine,[2] but it has not granted approval.

On June 24, 2021, Plaintiffs filed this lawsuit to prevent California State University (CSU) from implementing its policy "requir[ing] students . . . to get vaccinated against COVID-19 before the start of the fall semester." Compl., ECF No. 1, Ex. 1. CSU stated that its policy would

[1] July 7, 2021 Letter of Authorization to ModernaTX, Inc., https://go.usa.gov/xHFn3 (revising and reissuing prior EUA); June 25, 2021 Letter of Authorization to Pfizer Inc., https://go.usa.gov/xHFnT ("Pfizer EUA") (same); June 10, 2021 Letter of Authorization to Janssen Biotech, Inc, https://go.usa.gov/xFRGt (same).

[2] Pfizer & BioNTech, *U.S. FDA Grants Priority Review for the Biologics License Application for Pfizer-BioNTech COVID-19 Vaccine* (July 16, 2021), https://cdn.pfizer.com/pfizercom/2021-07/BLA_Acceptance_Media_Statement_FINAL.pdf; *see also* Moderna, *Moderna Announces Initiation of Rolling Submission of Biologics License Application (BLA) with U.S. FDA for the COVID-19 Vaccine* (June 1, 2021), https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-initiation-rolling-submission-biologics.

"be conditional upon one or more of the vaccines gaining full approval by the FDA," and that CSU would provide more information in the future, including about "exemptions." *Id.*

Plaintiffs are CSU students who are not vaccinated and allege they contracted COVID-19 in January 2020. *Id.* ¶¶ 21-24 & Decls. They assert two claims against Federal Defendants. Count II invokes 5 U.S.C. § 703 and seeks to enjoin Federal Defendants from issuing licensure of a COVID-19 vaccine without also requiring pre-screening for, and exclusion of, persons who currently have COVID-19 or have recovered from it ("recovered persons," and collectively, "pre-screening requirement").[3] Compl. ¶¶ 32-35; Prayer for Relief ¶ 2. Count III invokes 28 U.S.C. § 2201 and seeks declaratory relief against all defendants. Compl. ¶¶ 36-39.

On July 19, 2021—nearly a month after filing their complaint but before serving it on Federal Defendants—Plaintiffs filed their motion for preliminary injunction. ECF No. 5, 5-1 ("PI Mem."). Shortly thereafter, on July 29, 2021, CSU issued a policy that is no longer conditioned on final approval of a BLA, but proceeds in the meantime based on the EUAs.[4] Subject to medical and religious exemptions, students must certify full vaccination against COVID-19 by September 30, 2021, in order to access campus facilities.[5]

## LEGAL STANDARDS

In a "facial" challenge to the complaint under Rule 12(b)(1), a defendant "accepts the truth of the plaintiff's allegations but asserts that they 'are insufficient on their face to invoke federal jurisdiction.'" *Leite v. Crane Co.*, 749 F.3d 1117, 1121 (9th Cir. 2014) (quotation omitted). The court in turn applies the ordinary pleading standards, asking whether the plaintiff has plausibly

[3] Because Plaintiffs do not expressly challenge the actions of Federal Defendants other than FDA and the Centers for Disease Control and Prevention (CDC), *see, e.g.* PI Mem. at 3, 5 & n.3, this response addresses the roles of those two agencies. Also, the Complaint purports to name Secretary Becerra, Dr. Woodcock, and Dr. Fauci as defendants in both their official and personal capacities. Compl. ¶¶ 9-11. But federal officials cannot be sued in their personal capacity where, as here, a suit seeks only injunctive or declaratory relief that would "require[] official government action." *See Solida v. McKelvey*, 820 F.3d 1090, 1091-94 (9th Cir. 2016).

[4] *See* CSU, COVID-19 Vaccination Interim Policy §§ II.A, C (July 29, 2021), https://calstate.policystat.com/policy/9779821/latest/ ("CSU Policy").

[5] *See id.* §§ II.C, F; III.A, C, D.

pleaded the requisite jurisdictional elements. *See id.* The court "need not . . . accept as true allegations that contradict matters properly subject to judicial notice or by exhibit."[6] *Saldana v. Occidental Petrol. Corp.*, 774 F.3d 544, 551 & n.1 (9th Cir. 2014) (per curiam) (alteration in original; quotation omitted); *see also Hyatt v. Lee*, 871 F.3d 1067, 1071 n.15 (9th Cir. 2017).

To secure the "extraordinary and drastic remedy" of a preliminary injunction, *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam) (quotation omitted), ordinarily a plaintiff "must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest," *Winter v. NRDC*, 555 U.S. 7, 20 (2008). Alternatively, if the plaintiff fails to establish a *likelihood* of success, then he must at least identify "serious questions going to the merits." *Shell Offshore, Inc. v. Greenpeace, Inc.*, 709 F.3d 1281, 1291 (9th Cir. 2013) (quotation omitted). But in that instance, the plaintiff's burden on the equities prong is heavier: "a preliminary injunction may still issue so long as 'the balance of hardships tips *sharply* in the plaintiff's favor' and the other two factors are satisfied." *Short v. Brown*, 893 F.3d 671, 675 (9th Cir. 2018) (quotation omitted). Under either standard, a plaintiff must make a "*clear showing*." *Mazurek*, 520 U.S. at 972 (quotation omitted).

## ARGUMENT

The Court should dismiss Plaintiffs' claims against Federal Defendants under Rule 12(b)(1) because the Court lacks jurisdiction. Yet even if Plaintiffs could establish jurisdiction over their claims, *still* they fail to make the "clear showing" necessary to secure preliminary injunctive relief. There is no likelihood, or even a "serious question," of Federal Defendants' actions infringing Plaintiffs' constitutional rights. This is so even without addressing Plaintiffs' dubious health claims about COVID-19 vaccines—claims that Plaintiffs never presented for agency consideration. Nor have Plaintiffs demonstrated that any theoretical irreparable harm is either likely to occur or attributable to Federal Defendants. Finally, the public interest in leaving

[6] Federal Defendants request that the Court take judicial notice of EUAs, government websites, and company announcements—all cited for "fact[s] that [are] not subject to reasonable dispute." *In re Icenhower*, 755 F.3d 1130, 1142 (9th Cir. 2014) (quoting Fed. R. Evid. 201(d)).

scientific decisions to scientific agencies weighs heavily against premature judicial interference with Federal Defendants' expert review of COVID-19 vaccines, so the equities tip sharply in Federal Defendants' favor. Plaintiffs' motion should be denied.

## I. The Court Lacks Jurisdiction Over Claims Against Federal Defendants.

"Without jurisdiction the court cannot proceed at all in any cause." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) (quoting *Ex parte McCardle*, 74 U.S. (7 Wall.) 506, 514 (1868)); *see also* Fed. R. Civ. P. 12(h)(3). Here, the Court lacks jurisdiction over the claims against Federal Defendants because there is no final agency action, Plaintiffs lack Article III standing, the case is not ripe for review, the request for injunctive relief is moot, and there is no jurisdiction to issue a declaratory judgment. *See S.F. Herring Ass'n v. U.S. Dep't of Interior*, 946 F.3d 564, 571 (9th Cir. 2019) (final agency action); *Chandler v. State Farm Mut. Auto. Ins. Co.*, 598 F.3d 1115, 1121 (9th Cir. 2010) (standing and ripeness); *Ctr. for Biological Diversity v. Lohn*, 511 F.3d 960, 963 (9th Cir. 2007) (mootness); *Allen v. Milas*, 896 F.3d 1094, 1099 (9th Cir. 2018) (Declaratory Judgment Act). Plaintiffs' claims against Federal Defendants should be dismissed.[7]

### A. Plaintiffs Do Not Challenge Final Agency Action.

Plaintiffs seek to enjoin licensure of COVID-19 vaccines unless Federal Defendants issue a pre-screening requirement. Compl. ¶ 35; PI Mem. at 20. They also want Federal Defendants to "rescind their vaccination recommendation immediately." PI Mem. at 10; *see also id.* at 5, 15, 19; Compl. ¶ 19. But Plaintiffs have failed to identify a "final agency action" reviewable by this Court. *See* 5 U.S.C. § 704; *S.F. Herring*, 946 F.3d at 571.

Plaintiffs target approval and recommendation of vaccines, but neither of those activities meets the standard for final agency action.[8] The Supreme Court has identified "two conditions that generally must be satisfied for agency action to be 'final' under the [Administrative Procedure Act (APA)]." *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1813

[7] In the event the Court decides that it has jurisdiction, Federal Defendants reserve their right to raise certain non-jurisdictional defenses in a subsequent motion. *See* Fed. R. Civ. P. 12(h) (setting out grounds for waiver and preservation).

[8] Notably, Plaintiffs have not challenged the COVID-19 vaccine EUAs, the issuance of which is committed to agency discretion by law. *See* 21 U.S.C. § 360bbb-3(i).

(2016). "First, the action must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* (quotation omitted).

As Plaintiffs recognize, FDA has not approved a COVID-19 vaccine. PI Mem. at 12-13; *see also* Compl. ¶ 20; *compare* 21 U.S.C. § 360bbb-3 (EUA), *with* 42 U.S.C. § 262 (BLA).[9] Courts have repeatedly rebuffed efforts to interfere in ongoing FDA decisionmaking—including whether to approve a BLA—before FDA reaches a final decision. *See Cody Laboratories, Inc. v. Sebelius*, No. 10-CV-147-J, 2010 WL 11505836, at *4 (D. Wyo. Nov. 16, 2010) (holding that courts lack jurisdiction to consider FDA's review of an application until FDA has approved or denied the application); *CareToLive v. von Eschenbach*, 525 F. Supp. 2d 938, 949 (S.D. Ohio 2007) (same specifically for review of a BLA), *aff'd*, 290 F. App'x 887 (6th Cir. 2008). The same should apply here, because Plaintiffs do not challenge final agency action with respect to vaccine BLA approval.

Nor do federal recommendations regarding the use of vaccines that have received an EUA qualify as final agency action. First, they do not satisfy the threshold requirement of "agency action," because they are not "fairly analogous" to a "'rule, order, license, sanction, [or] relief.'" *Wild Fish Conservancy v. Jewell*, 730 F.3d 791, 801 (9th Cir. 2013) (alteration in original) (quoting 5 U.S.C. § 551(13)). Second, the recommendations are "purely advisory and in no way affect[] the legal rights of the relevant actors." *Bennett v. Spear*, 520 U.S. 154, 178 (1997); *see also Null v. FDA*, No. 09-CV-1924, 2009 WL 10744069, at *3 (D.D.C. Nov. 10, 2009) (State independently decides whether to require FDA-licensed vaccine). Because Plaintiffs have not challenged any final agency action, their claims against Federal Defendants should be dismissed.

**B. Plaintiffs Lack Article III Standing.**

"Before reaching the merits" of a motion for preliminary injunction, a court "must

[9] *See also* FDA News Release, Coronavirus (COVID-19) Update: July 16, 2021, https://go.usa.gov/xFRGS (announcing formal acceptance and priority review of BLA for Pfizer-BioNTech COVID-19 vaccine).

determine whether any plaintiff has standing." *Cal. Trucking Ass'n v. Bonta*, 996 F.3d 644, 652 (9th Cir. 2021). To satisfy Article III, Plaintiffs must establish that they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant[s], and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992)). "At this very preliminary stage, plaintiffs may rely on the allegations in their Complaint and whatever other evidence they submitted in support of their preliminary-injunction motion to meet their burden." *Cal. Trucking*, 996 F.3d at 652-53 (quotation omitted). But plaintiffs must at least satisfy their ordinary burden at the pleading stage: to "plausibly and clearly allege" each element of standing, *Thole v. U.S. Bank N.A.*, 140 S. Ct. 1615, 1621-22 (2020). This showing is necessary "for each claim" and "each form of relief," *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006), as well as for each defendant, *see, e.g.*, *Easter v. Am. W. Fin.*, 381 F.3d 948, 961-62 (9th Cir. 2004).

Plaintiffs fail to plausibly allege injury in fact. To support standing, an injury must be "concrete, particularized, and actual or imminent." *Thole*, 140 U.S. at 1618. The standard for imminence is a "certainly impending" harm or a "substantial risk" of harm. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014). Harm contingent on "a highly attenuated chain of possibilities" does not meet that standard. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410, 414 n.5 (2013). Plaintiffs do not allege any actual harm to date. Rather, they allege future harms in the form of anticipated adverse effects of COVID-19 vaccination. *See, e.g.*, Compl. ¶ 35. But they fail to adequately plead that any such harms are *imminent*.

Plaintiffs' alleged harms are merely speculative. Under Plaintiffs' theory, their injuries will come to fruition sometime after the "full" licensure of a COVID-19 vaccine, which they assert vaguely will happen in "the immediate future." *See, e.g.*, *id.* ¶ 20. Until vaccines are licensed, Plaintiffs can only guess whether Federal Defendants will issue a pre-screening requirement. *See id.* If Federal Defendants do not take the action Plaintiffs request, it would be up to CSU to independently decide whether recovered persons must receive a vaccine to access campus in-person. *See id.* ¶ 25; CSU Policy, *supra* note 4. If CSU requires recovered persons to do so, then Plaintiffs may seek a medical or religious exemption, and CSU must decide whether they qualify.

*See* Compl. Ex. 1; CSU Policy, *supra* note 4. If Plaintiffs are denied, at the end of the chain of possibilities is the speculation that the vaccine actually would harm Plaintiffs—a remote possibility. Agency expertise is necessary to fully assess Plaintiffs' scientific claims, *see infra* pp. 9-10, but the Court may take judicial notice that Plaintiffs' alleged probability of harm is flatly contradicted by CDC analysis.[10] Given the speculative series of events necessary to culminate in actual harm to Plaintiffs, they fail to establish Article III standing, so their claims should be dismissed.

Even if Plaintiffs could establish imminent injury, that injury would not be fairly traceable to the federal government's vaccination recommendation, as Plaintiffs suggest. *See* Compl. ¶ 19; PI Mem. at 3. FDA may approve COVID-19 vaccines, and CDC may recommend them, but none of the Federal Defendants requires their use. For standing purposes, therefore, the source of Plaintiffs' alleged injury is not any federal action, but the policy issued by CSU, a separate non-federal defendant.

A party cannot maintain standing to sue the federal government based on injuries caused by the conduct of third parties unless the government's actions have a "determinative," "coercive," or "predictable" effect on the third party's actions. *See Dep't of Com. v. New York*, 139 S. Ct. 2551, 2565-66 (2019); *Bennett*, 520 U.S. at 167-70; *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-43 (1976). Federal recommendations regarding COVID-19 vaccination have not determined or coerced the vaccination policy at CSU, nor is CSU's policy the predictable result of the federal recommendations. Many States and other entities have chosen not to impose similar vaccination orders—and some have affirmatively blocked such orders. *See, e.g.*, *Klaassen v. Trs. of Ind. Univ.*, No. 1:21-CV-238 DRL, 2021 WL 3073926, at *4 (N.D. Ind. July 18, 2021) (noting Ohio law prohibiting mandatory vaccine orders). As a State-associated entity, CSU makes decisions independently of Federal Defendants' actions, *see infra* pp. 15-16, in this

[10] *See* CDC, *Selected Adverse Events Reported after COVID-19 Vaccination*, https://go.usa.gov/xFR7q (Aug. 2, 2021) ("VAERS received 6,490 reports of death (0.0019%) among people who received a COVID-19 vaccine" through August 2, 2021). The EUAs mandate reporting of all serious adverse events, including death, "irrespective of attribution to vaccination." *See, e.g.*, Pfizer EUA at 7.

case by establishing a policy for particular populations as well as providing specific exemptions. Under these circumstances, Plaintiffs' alleged harms are not fairly traceable to the actions of Federal Defendants. *See Null*, 2009 WL 10744069, at *3 (State's influenza vaccine mandate not fairly traceable to FDA approval); *Goico v. FDA*, No. 20-1248-JAR-KGG, 2020 WL 7078731, at *7-8 (D. Kan. Dec. 3, 2020) (same for state regulators' and doctors' decisions about using hydroxychloroquine for COVID-19); *see also San Diego Cty. Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1130 (9th Cir. 1996) (no standing to sue federal defendants, where gun price increases were affected by state legislation and controlled by third-party dealers). Plaintiffs therefore lack Article III standing, and their claims should be dismissed.

**C. This Action Is Not Ripe Absent Approval of a COVID-19 Vaccine.**

For similar reasons, the claims against Federal Defendants are not ripe. *See Trump v. New York*, 141 S. Ct. 530, 535 (2020) (per curiam) ("[T]his case is riddled with contingencies and speculation that impede judicial review."). Ripeness doctrine is "designed to 'prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements,'" and it includes constitutional and prudential components. *Thomas v. Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1138 (9th Cir. 2000) (en banc) (quotation omitted).

Plaintiffs cannot establish the constitutional component of ripeness because of the lack of imminent harm from any challenged action of the Federal Defendants, as discussed above. *See, e.g.*, *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128 & n.8 (2007) (observing that "standing and ripeness boil[ed] down to the same question" of imminence of harm). Due to this constitutional deficiency, the Court need not reach prudential ripeness. *Ass'n of Am. R.R. v. Cal. Office of Spill Prevention & Response*, 113 F. Supp. 3d 1052, 1057 n.5 (E.D. Cal. 2015) (Nunley, J.) (citing *Mont. Env't Info. Ctr. v. Stone-Manning*, 766 F.3d 1184, 1188 n.3 (9th Cir. 2014)).

But the prudential component is also deficient because its factors are not satisfied. *See, e.g.*, *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 733 (1998) (identifying "'the fitness of the issues for judicial decision' and the 'hardship to the parties of withholding court consideration'" (quotation omitted)); *Thomas*, 220 F.3d at 1141. At the most basic level, the case is not fit for resolution absent "final agency action." *See supra* pp. 4-5; *Ass'n of Am. Med. Colls.*

*v. United States*, 217 F.3d 770, 780 (9th Cir. 2000); *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 943 n.4 (D.C. Cir. 2012). To analyze fitness and hardship, the Supreme Court has considered "(1) whether delayed review would cause hardship to the plaintiffs; (2) whether judicial intervention would inappropriately interfere with further administrative action; and (3) whether the courts would benefit from further factual development of the issues presented." *Ohio Forestry*, 523 U.S. at 733. None of those factors is satisfied here.

*First*, deferring review of the claims against Federal Defendants would not impose hardship on Plaintiffs, where Plaintiffs have limited their claims to an approval that has not occurred. Plaintiffs "may protect all of their rights and claims" about approval of a COVID-19 vaccine "by returning to court when the controversy ripens." *Atl. States Legal Found., Inc. v. EPA*, 325 F.3d 281, 285 (D.C. Cir. 2003).

*Second*, judicial review would short-circuit an administrative review process required by FDA regulations. "[A]s a prerequisite to judicial review" of APA claims, a plaintiff must exhaust an available administrative remedy "to the extent that it is required by statute or agency rule." *Darby v. Cisneros*, 509 U.S. 137, 153 (1993) (discussing 5 U.S.C. § 704); *see also Idaho Sporting Cong., Inc. v. Rittenhouse*, 305 F.3d 957, 965 (9th Cir. 2002). FDA regulations require engaging FDA's citizen petition process before filing a lawsuit "complaining of [a requested administrative] action or failure to act." 21 C.F.R. § 10.45(b); *see Ctr. for Food Safety v. Hamburg*, 696 F. App'x 302, 303 (9th Cir. 2017) (mem.); *Cody Laboratories, Inc. v. Sebelius*, 446 F. App'x 964, 969 (10th Cir. 2011). Complying with this requirement is "especially important" where "allowing the litigants to proceed in federal court would deprive the agency of *any* opportunity to exercise its discretion or apply its expertise." *Ass'n of Flight Attendants-CWA v. Chao*, 493 F.3d 155, 159 (D.C. Cir. 2007); *see also Buckingham v. Sec'y of U.S. Dept. of Agr.*, 603 F.3d 1073, 1080 (9th Cir. 2010).

Here, Plaintiffs have not alleged that they submitted a citizen petition to FDA regarding a pre-screening requirement.[11] Yet their request calls for an evaluation of technical and scientific

[11] Had Plaintiffs submitted a citizen petition, FDA would be able to consider it alongside any other relevant citizen petitions currently pending. *See* PI Mem. at 18; *infra* note 12.

information of the type within FDA's core area of expertise. *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983); *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 653-54 (1973). Enforcing Plaintiffs' obligation to file a petition would "ensure that the agency possessed of the most expertise" has the "first shot at resolving [Plaintiffs'] difficulties." *Idaho Sporting*, 305 F.3d at 965. And Plaintiffs would suffer no prejudice by filing a citizen petition—FDA is empowered to grant Plaintiffs' requested relief, and it has responded to and is considering other citizen petitions involving COVID-19 vaccines.[12]

*Third*, requiring Plaintiffs to file a citizen petition first with FDA would also provide the Court with an administrative record that includes FDA's evaluation of Plaintiffs' evidentiary claims regarding COVID-19 vaccines. Indeed, review of agency action under the APA is generally limited to the administrative record, rather than extrinsic evidence. *Goffney v. Becerra*, 995 F.3d 737, 747-48 (9th Cir. 2021). FDA's assessment would be entitled to great deference, as it requires "making predictions, within its area of special expertise, at the frontiers of science." *Friends of Santa Clara River v. U.S. Army Corps of Eng'rs*, 887 F.3d 906, 921 (9th Cir. 2018) (cleaned up). Absent constitutional or prudential ripeness, dismissal is required.

**D. Plaintiffs' Request for Injunctive Relief Is Moot.**

CSU's policy mooted Plaintiffs' request to enjoin Federal Defendants from issuing a BLA absent a pre-screening requirement, and therefore the Court lacks jurisdiction to issue such relief. "A case becomes moot—and therefore no longer a 'Case' or 'Controversy' for purposes of Article III—'when the issues presented are no longer "live" or the parties lack a legally cognizable interest in the outcome.'" *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 90-91 (2013) (quotation omitted); *see also Bayer v. Neiman Marcus Grp., Inc.*, 861 F.3d 853, 862 (9th Cir. 2017) (asking whether "effective relief can be granted" (quotation omitted)). Courts make this

[12] *See*, *e.g.*, Citizen Petition, Dkt. No. FDA-2020-P-1770, Docs. 01 (Petition, Aug. 17, 2020), 04 (Petition for Stay of Action, Aug. 19, 2020), 13 (Amended Petition, Oct. 16, 2020), 37 (Response, Dec. 14, 2020) (responding to a request, among others, that clinical studies to support EUA of the Pfizer COVID-19 vaccine screen participants for T-Cell reactivity to SARS-CoV-2 to assess whether pre-existing immunity to COVID-19 might be detrimental); Citizen Petition, Dkt. No. FDA-2021-P-0460 (May 16, 2021) (requesting certain action as to EUAs and BLAs).

inquiry separately for each cause of action. *See Bayer*, 861 F.3d at 864-69. "A plaintiff who cannot reasonably be expected to benefit from prospective relief ordered against the defendant has no claim for an injunction." *Id*. at 864.

CSU's policy proceeds based on the (already-granted) EUAs, rather than awaiting the (not-yet approved) BLAs. As such, enjoining Federal Defendants from issuing a BLA absent a pre-screening requirement would not affect whether Plaintiffs receive a vaccine or afford them effective relief.[13] And absent the potential for effective relief, Plaintiffs no longer have a legally cognizable interest in issuance of the BLA—with or without pre-screening. *See Already*, 568 U.S. at 90-91. Plaintiffs have not challenged the EUAs; nor could they, as "emergency-use authorizations are exempt from review under the APA." *Ass'n of Am. Physicians & Surgeons v. U.S. FDA*, No. 20-1784, 2020 WL 5745974, at *3 (6th Cir. Sept. 24, 2020) (citing 5 U.S.C. § 701(a)(2); 21 U.S.C. § 360bbb-3(i)). The Court therefore cannot grant Plaintiffs any effective injunctive relief against Federal Defendants, and it should dismiss Count II. *See, e.g., Ctr. for Biological Diversity*, 511 F.3d at 963-64 (changed circumstances mooted injunctive relief).

**E. The Court Lacks Jurisdiction Over Count III.**

Count III seeks declaratory relief, which would address "whether vaccination of those who have either had the virus, or currently have the virus, are at risk of death or serious illness." Compl. at 1, li.19-21. This Count must be dismissed not only because of the jurisdictional defects discussed above, but also because none of the six federal statutes cited in the Complaint supplies subject-matter jurisdiction over this Count against Federal Defendants.

Count III rests on the Declaratory Judgment Act (DJA), 28 U.S.C. § 2201, but the DJA "alone does not provide a court with jurisdiction," so an Article III case or controversy must be established. *California v. Texas*, 141 S. Ct. 2104, 2115 (2021). Because standing and ripeness are part of "the absolute constitutional minimum for a justiciable controversy," *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1336 (Fed. Cir. 2008), their absence here shows that the

[13] The Court also cannot compel issuance of the BLA with a pre-screening requirement, because that would require Plaintiffs to satisfy the mandamus criteria, which they do not. *See infra* pp. 13-14.

DJA claim lacks the "immediacy and reality" of a justiciable controversy, *id.* at 1338 (quoting *MedImmune*, 549 U.S. at 127). The Court thus lacks jurisdiction over the DJA claim.

Moreover, the DJA "creates only a remedy, not a cause of action," *Allstate Ins. Co. v. Am. Reliable Ins. Co.*, No. 16-cv-00871-TLN-KJN, 2017 WL 1153041, at *4 (E.D. Cal. Mar. 28, 2017) (quotation omitted), so it is insufficient to ground federal question jurisdiction under 28 U.S.C. § 1331, *see Am. States Ins. Co. v. Kearns*, 15 F.3d 142, 143 (9th Cir. 1994).

Asserting jurisdiction under the APA, mandamus, and two civil rights statutes is plainly incorrect. Plaintiffs invoke 5 U.S.C. § 703, but this provision is not "an independent grant to district courts of subject-matter jurisdiction to review a decision" of federal agencies or officials. *Califano v. Sanders*, 430 U.S. 99, 100-01 (1977); *see also id.* at 105, 107 (rejecting view that APA is "an implied grant of subject-matter jurisdiction"). Likewise, the mandamus statute "does not provide an independent ground for jurisdiction." *Villa v. Jewell*, No. 2:16-CV-00503-KJM-KJN, 2017 WL 1093938, at *2 (E.D. Cal. Mar. 23, 2017) (quoting *Starbuck v. City of San Francisco*, 556 F.2d 450, 459 n.18 (9th Cir. 1977)). That leaves the federal civil rights statutes, which concern alleged violations "under color of any State law," 28 U.S.C. § 1343(a)(3); *see also* 42 U.S.C. § 1983, and which Plaintiffs do not attribute to Federal Defendants. Absent any jurisdictional hook for Count III against Federal Defendants, that claim must be dismissed.

## II. Plaintiffs Are Not Entitled to the Extraordinary Relief of a Preliminary Injunction.

If the Court decides that it has jurisdiction over claims against Federal Defendants, it should still deny Plaintiffs' motion because Plaintiffs cannot satisfy the standard for preliminary relief.

### A. Plaintiffs Have No Likelihood of Success on the Merits.

Plaintiffs seek injunctive relief on the grounds that Federal Defendants will violate their due process rights by licensing a COVID-19 vaccine without a pre-screening requirement. Compl. ¶ 35, Prayer for Relief ¶ 2; PI Mem. at 20. But Plaintiffs are not entitled to this relief because FDA's vaccine approval is not subject to mandamus and, ultimately, Federal Defendants will not deprive Plaintiffs of any constitutional rights. The "complete lack of probability of success or serious questions going to the merits" is enough to deny the motion. *Glob. Horizons, Inc. v. U.S. Dep't of Lab.*, 510 F.3d 1054, 1057-58 (9th Cir. 2007).

**1. Writ of Mandamus**

Although Plaintiffs style their motion as seeking a negative injunction, they in fact ask the Court to compel Federal Defendants to take specific *affirmative* acts—namely, adopt a pre-screening requirement. Given Plaintiffs' requested relief and their invocation of 28 U.S.C. § 1361 as a basis for jurisdiction (Compl. ¶ 1), the relief is properly characterized as seeking a writ of mandamus. *Or. Nat. Res. Council v. Harrell*, 52 F.3d 1499, 1508 (9th Cir. 1995) ("When the effect of a mandatory injunction is the equivalent of mandamus, it is governed by the same standard.").

"Mandamus is an extraordinary remedy and is available to compel a federal official to perform his duty only if: (1) the individual's claim is clear and certain; (2) the official's duty is nondiscretionary, ministerial, and so plainly prescribed as to be free from doubt, and (3) no other adequate remedy is available." *Kildare v. Saenz*, 325 F.3d 1078, 1084-85 (9th Cir. 2003).[14] "Even if the test is met, the district court still retains the discretion to deny relief." *Johnson v. Reilly*, 349 F.3d 1149, 1154 (9th Cir. 2003).

Determining the conditions on which to approve a COVID-19 vaccine is plainly not a "nondiscretionary and ministerial" act that gives rise to "clear and certain" rights for Plaintiffs. Congress entrusted FDA with determining whether new vaccines identified in BLAs are "safe, pure, and potent" for preventing illness. 42 U.S.C. § 262(a)(2)(C)(i); *see also id.* § 262(i)(1). In that role, FDA uses its expertise to evaluate scientific and technical information, such as studies and clinical trials. *E.g.*, 21 C.F.R. § 601.2. A BLA issues only upon FDA's determination that an application satisfies applicable requirements, *id.* § 601.4, and courts are highly deferential to the agency's scientific determinations, *Friends of Santa Clara River*, 887 F.3d at 921. A pre-screening requirement is thus not subject to mandamus. *See Arvizu v. Acosta,* No. 1:17-CV-219-LJO-EPG, 2017 WL 3421976, at *5 (E.D. Cal. Aug. 9, 2017) ("The plain language of the statutes and regulations . . . indicate[s] that the determination of whether to issue the FLC

[14] *See also Stanley v. Univ. of S. Cal.*, 13 F.3d 1313, 1320 (9th Cir. 1994) ("A mandatory injunction 'goes well beyond simply maintaining the status quo *pendente lite* [and] is particularly disfavored.'" (quotation omitted)).

certificates is a discretionary, non-ministerial task that is not subject to a writ of mandamus."). And even if it were, at least one other remedy remains available: Plaintiffs can file a citizen petition with FDA, so they have not "exhausted all other avenues of relief." *Heckler v. Ringer*, 466 U.S. 602, 616 (1984). Mandamus is therefore unavailable.

**2. Substantive Due Process**

Plaintiffs' underlying due process theory also fails. "The touchstone of due process is protection of the individual against arbitrary action of government." *Disbar Corp. v. Newsom*, 508 F. Supp. 3d 747, 752 (E.D. Cal. 2020) (Nunley, J.) (quoting *Wolff v. McDonnell*, 418 U.S. 539, 558 (1974)). "To succeed on a substantive or procedural due process claim, the plaintiffs must first establish that they were deprived of an interest protected by the Due Process Clause." *Johnson v. Rancho Santiago Cmty. Coll. Dist.*, 623 F.3d 1011, 1029 (9th Cir. 2010). Plaintiffs must provide a "careful description" of the asserted interest, and "vague generalities . . . will not suffice." *Chavez v. Martinez*, 538 U.S. 760, 775-76 (2003) (cleaned up). Moreover, "[t]o constitute a violation of substantive due process, the alleged deprivation must 'shock the conscience and offend the community's sense of fair play and decency.'" *Sylvia Landfield Tr. v. City of Los Angeles*, 729 F.3d 1189, 1195 (9th Cir. 2013) (quotation omitted).

Plaintiffs' due process theory fails to raise a serious question for at least four reasons. *First*, courts have described as "absurd and not worthy of serious discussion" the notion that measures "designed to save human lives [from COVID-19]" shock the conscience. *Herrin v. Reeves*, No. 3:20CV263-MPM-RP, 2020 WL 5748090, at *9 (N.D. Miss. Sept. 25, 2020); *see also Disbar*, 508 F. Supp. 3d at 752 (determining that California's COVID-19 restrictions do not shock the conscience). That holds true here, as Federal Defendants' licensing of COVID-19 vaccines and making related recommendations are intended to save lives.

*Second*, Plaintiffs have not shown that a protected interest is at stake. Plaintiffs claim that Federal Defendants "have a mandatory duty under the due process clause to notify potential recipients of the vaccines of the serious health effects, including death, if they are a [recovered person]." Compl. ¶ 34; *see also* PI Mem. at 15-19. Plaintiffs assert a right to require Federal Defendants to notify the public of particular health warnings, but Plaintiffs do not show that such

a purported right is "deeply rooted in this Nation's history and tradition," or that without it "neither liberty nor justice would exist." *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997) (quotations omitted).

*Third*, even if Plaintiffs' interests were constitutionally protected, Plaintiffs have not established that Federal Defendants' actions infringe on those interests. FDA's licensure of a vaccine BLA is now irrelevant to Plaintiffs' asserted interests because CSU's vaccine policy is not contingent on licensure. *See* CSU Policy, *supra* note 4. Plaintiffs may respond that Federal Defendants remain responsible because CSU allegedly "relied" upon or "adopted" Federal Defendants' "official recommendations." Compl. ¶ 19; PI Mem. at 3, 19. But States have the independent authority to enact laws that "provide for the public health, safety, and morals." *Barnes v. Glen Theatre*, 501 U.S. 560, 569 (1991); *accord Jacobson v. Massachusetts*, 197 U.S. 11, 24-25 (1905). States and associated entities are free to accept or reject federal recommendations. *See*, *e.g.*, *Null*, 2009 WL 10744069, at *3 (citing *Jacobson*, 197 U.S. at 35). In other words, "just because the federal government approved a vaccine as safe for human consumption," that does not cause the alleged harm, because CSU is the non-federal entity "actually requiring the plaintiffs to submit to the vaccination," *id.*, absent exemption, for in-person access. Plaintiffs thus cannot show that Federal Defendants' actions will deprive them of any protected interest. *See, e.g.*, *Rancho Santiago*, 623 F.3d at 1029-30 (rejecting due process claims absent a showing that plaintiffs were deprived of their fundamental interest).

*Fourth*, even assuming Federal Defendants' actions infringe on a constitutionally protected interest, they easily clear rational basis review, which is the proper standard to apply. The Supreme Court has long instructed that courts are to generally avoid disturbing the judgment of public health officials, *Jacobson*, 197 U.S. at 25-26; *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007), and it has reaffirmed this principle during the COVID-19 pandemic. *See FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) ("*ACOG*") (Roberts, C.J., concurring in grant of application for stay) (emphasizing that "courts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health'" (quotation omitted)). The Court has further observed that "[s]temming the spread

of COVID-19 is unquestionably a compelling interest." *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020); *accord Disbar*, 508 F. Supp. 3d at 754. Accordingly, courts routinely dismiss due process challenges to public health measures, including to vaccine requirements, on rational basis review. *See, e.g.*, *Klaassen*, 2021 WL 3073926, at *26-38.

Even if Federal Defendants' actions were examined under higher scrutiny, they are narrowly tailored to the compelling interest—Federal Defendants authorized the emergency use of COVID-19 vaccines and made recommendations regarding use, while decisions about vaccine mandates remain with States or other entities. *See Jacobson*, 197 U.S. at 38; *Barnes*, 501 U.S. at 569. Moreover, courts have upheld many COVID-19 measures that actually place affirmative restrictions on individuals,[15] and recognized that *Jacobson* "foreclosed" due process challenges to vaccine requirements, *Phillips v. City of New York*, 775 F.3d 538, 542 (2d Cir. 2015).

Absent even a serious question on the merits,[16] "no further determination of irreparable harm or balancing of hardships is necessary." *Glob. Horizons*, 510 F.3d at 1058.

**F. Plaintiffs Fail to Demonstrate a Likelihood of Irreparable Harm.**

The irreparable harm factor is "the single most important prerequisite for the issuance of a preliminary injunction." *Smith v. San Joaquin Cty. Mental Health Servs.*, No. 2:16-cv-00884-TLN-KJN, 2016 WL 1720744, at *3 (E.D. Cal. Apr. 29, 2016) (quoting *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 114 (2d Cir. 2005)). To clear the threshold, Plaintiffs must "demonstrate that irreparable harm is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22.

[15] *See, e.g., Disbar*, 508 F. Supp. 3d at 752-55 (denying temporary restraining order based on due process challenge to California's COVID-19 restrictions); *Klaassen*, 2021 WL 3073926, at *38-41 (upholding university's COVID-19 vaccine requirement); *Aviles v. Blasio*, No. 20 CIV. 9829 (PGG), 2021 WL 796033, at *17-18 (S.D.N.Y. Mar. 2, 2021) (upholding city order requiring students to undergo testing for COVID-19, because the "testing regime is reasonably related to a legitimate state objective – curbing the spread of the COVID-19 virus"); *Tandon v. Newsom*, No. 20-CV-07108-LHK, 2021 WL 411375, at *16-18 (N.D. Cal. Feb. 5, 2021) (upholding California's COVID-19 restrictions), *appeal docketed*, No. 21-15228 (9th Cir. Feb. 9, 2021); *Six v. Newsom*, 462 F. Supp. 3d 1060, 1069-70 (C.D. Cal. 2020) (similar).

[16] Plaintiffs' assertion of a disability (PI Mem. at 5) from past COVID-19 infection fails as they do not allege any long-term effects that substantially limit a major life activity. *See, e.g.*, *Wong v. Regents of Univ. of Cal.*, 410 F.3d 1052, 1063 (9th Cir. 2005); *Champion v. Mannington Mills, Inc.*, No. 5:21-CV-00012-TES, 2021 WL 2212067, at *3 (M.D. Ga. May 10, 2021).

Speculating that harm is imminent does not suffice. *Caribbean Marine Servs. Co. v. Baldrige*, 844 F.2d 668, 674 (9th Cir. 1988).

A plaintiff must also demonstrate that there is a "sufficient causal connection" between the alleged irreparable harm and the activity to be enjoined. *Perfect 10, Inc. v. Google, Inc.*, 653 F.3d 976, 982 (9th Cir. 2011). "While a plaintiff need not 'show that the action sought to be enjoined is the *exclusive* cause of the injury,'" courts appropriately deny a preliminary injunction request where the alleged harm does not "flow from" defendant's conduct. *Fox Broad. Co. v. Dish Network L.L.C.*, 747 F.3d 1060, 1072-73 (9th Cir. 2014) (emphasis added) (quotations omitted).

Here, Plaintiffs allege that defendants' actions will irreparably deprive them of their due process rights because either (i) "[d]eprivation of constitutional rights for *even minimal periods of time*, unquestionably constitutes irreparable injury," or (ii) "[t]he existence of a *continuing* constitutional violation constitutes proof of an irreparable harm." PI Mem. at 3-4 (emphases added). Yet Plaintiffs fail to carry their burden because they have not shown that any injury is likely or that Federal Defendants' actions would cause such harm.[17]

Plaintiffs' theory of harm hinges on a long series of speculative events, demonstrating that any harm is *not* imminent. As described in the standing discussion, several alternative outcomes—such as a contraindication from FDA or a medical exemption from CSU—could end up relieving Plaintiffs from the vaccination requirement. Because it is far from certain that Plaintiffs will be required to take a COVID-19 vaccine to maintain CSU in-person access, they cannot establish that irreparable harm is *likely*.

Even if Plaintiffs could somehow dispel the speculation and confirm they will have to take the vaccine to access campus, they still cannot show that Federal Defendants' conduct has deprived them of any constitutional rights. As discussed above, Plaintiffs have a low likelihood of success on their due process claims because, among other things, courts routinely uphold public health measures in the face of constitutional challenges. Moreover, Federal Defendants

[17] In light of Plaintiffs' bare assertions in affidavits that they "do not consent to receive the experimental vaccine" without further discussion of harm, PI Mem. Exs. 4-6, it is questionable whether they have adequately demonstrated potential for harm at all. *See* L.R. 231(d)(2).

have not imposed any vaccine *mandates* on Plaintiffs—Federal Defendants' conduct is limited to vaccine evaluation and recommendations—so any injuries to Plaintiffs' constitutional rights would not "flow from" Federal Defendants' conduct.[18] *Fox Broad. Co.*, 747 F.3d at 1072-73.

Because Plaintiffs have not shown that irreparable harm is likely or attributable to Federal Defendants, Plaintiffs fail on this crucial prong of the *Winter* standard.

**G. The Balance of Equities and Public Interest Support Denying Plaintiffs' Motion.**

"When the government is a party, these last two factors [of the *Winter* test] merge." *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014) (citing *Nken v. Holder*, 556 U.S. 418, 435 (2009)). The Court therefore determines whether the public interest weighs in favor of, or against, an injunction. *See id.* Even when "irreparable injury may otherwise result to [a] plaintiff," courts have discretion to deny an injunction that would "adversely affect a public interest." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312-13 (1982) (quotation omitted). In this case, the public interest is clear: ending the COVID-19 pandemic, in part through FDA's approval of safe vaccines and CDC's broad promotion of vaccination.

As part of FDA's role of assessing vaccine safety, purity, and potency, FDA determines whether safety concerns should preclude administration of a vaccine to certain subpopulations. Specifically, FDA evaluates a manufacturer's proposed labeling for the vaccine, which must address any contraindications, defined as "any situations in which the drug should not be used because the risk of use (e.g., certain potentially fatal adverse reactions) clearly outweighs any possible therapeutic benefit." 21 C.F.R. § 201.57(a)(9), (c)(5). Such "situations include use of the drug in patients who, because of their particular . . . *disease state, or other condition*, have a substantial risk of being harmed by the drug and for whom no potential benefit makes the risk acceptable." *Id.* § 201.57(c)(5) (emphasis added).

[18] For similar reasons, Plaintiffs' claimed *per se* injury therefore fails. *See Ass'n for Accessible Meds. v. Becerra*, No. 2:19-CV-02281-TLN-DB, 2019 WL 7370421, at *4 (E.D. Cal. Dec. 31, 2019) ("The State is of course correct that absent a likelihood of success on the merits of its constitutional claims, Plaintiff's claimed *per se* injury resulting from a constitutional violation necessarily fails."), *vacated and remanded on other grounds*, 822 F. App'x 532 (9th Cir. 2020).

Currently, FDA is evaluating pending BLAs for at least one COVID-19 vaccine.[19] FDA will determine whether the data submitted with the application indicates that the "risk of use . . . clearly outweighs any possible therapeutic benefit" in any subpopulations. 21 C.F.R. § 201.57(c)(5). If so, FDA will require labeling to include corresponding contraindications. *See, e.g.*, *id.* § 201.57(c). Enjoining review and approval of a BLA would short-circuit FDA's scientific review and potentially deny an approved vaccine to the entire country. Similarly, CDC has responsibility for promoting preventive means of combatting diseases, such as COVID-19. *See, e.g.*, 42 U.S.C. § 241(a).[20] If CDC receives data indicating that recovered persons are at risk of serious adverse health effects from taking a COVID-19 vaccine, then CDC will issue any appropriate warning. The FDA and CDC processes should be allowed to run their course.

As discussed, courts often block attempts to disturb the judgment of public health officials during a pandemic. *See supra* pp. 15-16 & n.15. Those officials include Federal Defendants. Earlier this year, the Supreme Court stayed a preliminary injunction that would have compelled FDA to alter certain drug dispensing protocol "because of the [district] court's own evaluation of the impact of the COVID-19 pandemic." *ACOG*, 141 S. Ct. at 578-79 (Roberts, C.J., concurring in grant of application for stay). Deference is just as important here, where FDA has a statutory responsibility for assessing the safety, purity, and potency of a COVID-19 vaccine.

Turning to Plaintiffs' interest, they seek to avoid "serious illness and death," or a risk thereof, that they attribute to vaccinating recovered persons. PI Mem. at 1-2, 8-10. But securing a pre-screening requirement is not the only way of addressing that concern. *First*, Plaintiffs may file a citizen petition sharing any data about the risk that COVID-19 vaccines allegedly pose to recovered persons. 21 C.F.R. §§ 10.25(a), 10.30. *Second*, if a vaccine is approved without pre-screening, and CSU does not create an exception for recovered persons, then Plaintiffs can seek a medical or religious exemption. *See* Compl. Ex. 1; CSU Policy, *supra* note 4. And *third*,

[19] Pfizer & BioNTech, *supra* note 2; *see also* Moderna, *supra* note 2. After FDA approves a vaccine or issues an EUA, the vaccine continues to be studied to determine how well it works under real-world conditions. FDA, CDC, and other federal partners have been assessing, and will continue to assess, COVID-19 vaccine effectiveness under real-world conditions.

[20] *See also* 53 Fed. Reg. 36,644, 36,644 (Sept. 21, 1988) (delegation of authority to CDC).

Plaintiffs could "transfer to a different school, or forego school . . . altogether." *Klaassen*, 2021 WL 3073926, at *1, *25 (noting that this "hard choice doesn't amount to coercion," given other options, such as taking a vaccine or seeking exemption).

Properly understood, the public shares Plaintiffs' interest in avoiding serious adverse health effects from COVID-19 vaccines; that is one reason why FDA must be allowed to continue carefully studying their safety and CDC to continue to deliver appropriate preventive messages. The Court need not intervene in that process to ensure that FDA reaches the right conclusion about safety risks for the subpopulation of recovered persons. In short, the Court should reject Plaintiffs' attempt to usurp the role of the public health agencies. *See Va. Petrol. Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921, 925 (D.C. Cir. 1958) (per curiam) ("In litigation involving the administration of regulatory statutes designed to promote the public interest, . . . [t]he interests of private litigants must give way to the realization of public purposes.").

Moreover, enjoining Federal Defendants from granting approval to a vaccine—with nationwide effect—would be broadly detrimental to the vital public interest in vaccination against COVID-19. "An injunction must be 'narrowly tailored to remedy the specific harm shown.'" *E. Bay Sanctuary Covenant v. Barr*, 934 F.3d 1026, 1029 (9th Cir. 2019) (quotation omitted). A nationwide injunction is an exception allowed only when "necessary to remedy a plaintiff's harm." *Id.* Such a broad injunction is unnecessary here, where only the policies of CSU directly affect Plaintiffs.

In short, Plaintiffs seek to enjoin the approval of life-saving vaccines in the midst of a surge of COVID-19 cases across the country. Such an injunction would not prevent irreparable harm; it would hasten it. The public interest therefore weighs heavily against enjoining Federal Defendants.

## CONCLUSION

For the foregoing reasons, the Court should dismiss the claims against Federal Defendants under Rule 12(b)(1) for lack of jurisdiction. If the Court decides that it has jurisdiction, the Court should deny Plaintiffs' Motion for Preliminary Injunction.

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

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August 5, 2021

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